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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,182	01/10/2002	Frank Breitling	4121-126	8533
23448	7590	08/09/2006	EXAMINER	
INTELLECTUAL PROPERTY / TECHNOLOGY LAW			GRUN, JAMES LESLIE	
PO BOX 14329			ART UNIT	PAPER NUMBER
RESEARCH TRIANGLE PARK, NC 27709			1641	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/889,182	BREITLING ET AL.
	Examiner	Art Unit
	James L. Grun	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 July 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-14 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-14 and 21-24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 20 September 2005 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

The amendment filed 17 July 2006 is acknowledged and has been entered. Claims 1-14 and 21-24 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The drawings filed 20 September 2005 remain objected to for the reasons of record that Fig. 3B (cont'd IV) presents a jumbled sequence which does not depict the sequence, and is not consecutively numbered, as in the original. Specifically the sequence depicts, beginning at the bottom of Fig. 3B (cont'd III), residues 3305-3360, residues 3921-4312-3361-3920 in Fig. 3B (cont'd IV), and 4313-... in Fig. 3B (cont'd V). Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Submission of corrected drawings may no longer be held in abeyance pending the indication of allowable subject matter. Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

Applicant's arguments filed 17 July 2006 have been fully considered but they are not deemed to be persuasive. Applicant urges that, except for a change in font, the new figure 3B is identical to Fig. 3B as originally filed. This is not found persuasive because, as set forth previously and above, the sequence in the new figure does not correspond to that depicted in the original.

The specification is objected to and claims 1-14 and 21-24 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record, that the claims contain subject matter which was

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not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth, even if one assumes retention of the antibody binding protein in the hybrid cells, which is not predictable for the reasons of record, one would not be assured of the ability to select the desired producer cell(s) from the population because, absent further guidance from applicant, one would be unable to identify and specifically separate the secreting cell(s) from a population of cells which are all capable of binding the secreted product

Applicant's arguments filed 17 July 2006 have been fully considered but they are not deemed to be persuasive.

Applicant urges that the examiner's argument is based on the decision in *Genentech Inc. v. Novo Nordisk*, 42 USPQ 2d 1001 (CAFC 1997). This is not found persuasive because, although the examiner relied upon that decision for setting forth that "there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement", the basis of the examiner's consistent argument is that applicant's specification provides no written description or guidance for inhibiting the uptake of secreted antibodies by undesired non-secreting cells in the population, if the cells have the instantly disclosed antibody binding molecules expressed thereon, and, therefore, one would not be assured of the ability to select the desired producer cell(s) from the population because one

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would be unable to identify and specifically separate the secreting cell(s) from a population of cells which are merely capable of binding the secreted product. Notwithstanding applicant's assertions to the contrary, the examiner did not dispute "a large amount" of antibody binding proteins because this is not a claimed feature of the invention. The examiner questioned applicant's prior unsubstantiated and unsupported assertion that the antibody producing cells express antibodies on their surfaces which are pre-bound to the understood "large amount" of antibody binding proteins intracellularly, trapping the antibodies on the expressing cells, and thus that the producing cells can be distinguished from the non-producing cells by fluorescence analysis. Again, there is nothing found to support applicant's assertions of pre-binding or of sufficient quantities of binding protein to effectively intracellularly bind and trap all antibodies produced. The antibody binding proteins are not limited to intracellular binding by any disclosure of applicant, even a producer cell with antibody binding proteins thereon can secrete antibodies because there is nothing in evidence that co-expressed binding proteins effectively intracellularly bind and trap all antibodies produced, and the antibody binding proteins on one cell, a cell which may not make relevant antibodies, can bind antibodies secreted by other cells in the population, cells which may not, or may not continue to, express antibody binding protein constructs thereon.

Applicant further urges that cell selection by fluorescent activated cell sorting (FACS) is within the skill of the state of the art. This is not found persuasive for the reasons of record. The issue is not if one can select cells by FACS, the issue is whether the selected cells are the secreting cells of interest if nothing is done to inhibit the uptake of secreted antibodies by

undesired non-secreting cells having antibody binding molecules expressed on their surface. The examiner would also note that protein G binds goat IgG.

With further regard to the cited decision in *Genentech Inc. v. Novo Nordisk*, applicant urges that all that is required as a specific starting material is a myeloma cell line which is engineered to display antibody binding proteins, such as a X63-Ag8.653.3 myeloma cell line which exhibits a stable display of large amounts of protein G. This is not found persuasive for the reasons of record, as repeated above, regarding inadequate description and enablement for specifically separating the secreting cell(s) from a population of cells. And, further, applicant is arguing limiting features not found in the instantly rejected claims and not relied upon in any grounds of rejection. The examiner would note that the claims are not limited to a myeloma cell line which exhibits a stable display of large amounts of protein G, and in particular the X63-Ag8.653.3 myeloma cell line is not claimed. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The specification is objected to and claims 21-24, are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record that the instant claims contain subject matter which was not described in the specification, as originally filed, in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the invention as is now claimed.

Applicant's arguments filed 17 July 2006 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's prior assertions to the contrary, applicant's amendments have not obviated the rejection of these claims for the reasons of record and as noted above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JLG

James L. Grun, Ph.D.
August 2, 2006

Long Le

LONG V. LE 08/04/06
SUPERVISORY PATENT EXAMINER
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